



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0736]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on our use of a tracking network to collect and share safety information about animal food from Federal, State, and Territorial Agencies.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0736 for "Agency Information Collection Activities; Proposed Collection; Comment Request;

Tracking Network for PETNet, LivestockNet, and SampleNet." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Tracking Network for PETNet, LivestockNet, and SampleNet--OMB Control Number
0910-0680--Revision

The Center for Veterinary Medicine and the Partnership for Food Protection developed a web-based tracking network (the tracking network) to allow Federal, State, and Territorial regulatory and public health agencies to share safety information about animal food. Information is submitted to the tracking network by regulatory and public health agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk. The tracking network was developed under the requirements set forth under section 1002(b) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-085). Section 1002(b) of FDAAA required FDA, in relevant part, to establish a pet food early warning alert system.

Currently we receive two types of reports via the tracking network: (1) reports of pet food related illness and product defects associated with dog food, cat food, and food for other pets, which are submitted via the Pet Event Tracking Network (PETNet); and (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses, which are submitted via LivestockNet. We are revising the collection to include a third type of report that would be submitted via "SampleNet." SampleNet will collect reports about animal food laboratory samples considered adulterated by State or FDA regulators. SampleNet will allow Federal, State, and Territorial regulatory and

public health agencies to share laboratory data related to adulterated samples for purposes of surveillance, mitigation, work planning, and supporting the animal food standard requirements.

PETNet and LivestockNet reports share the following common data elements, the majority of which are drop down menu choices: Product details (product name, lot code, product form, and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (i.e., name, telephone number will be captured automatically when member logs in to the system). For the LivestockNet report, additional data elements specific to livestock animals will be captured: Product details (indication of whether the product is a medicated feed under 21 CFR 558.3(b)(8), product packaging, and intended purpose of the product), class of the animal species affected, and production loss. For PETNet reports, the only additional data field is the animal life stage. The proposed SampleNet reports will have the following data elements, many of which are drop down menu choices: Product information (product name, lot code, guarantor information, date and location of sample collection, and product description); laboratory information (sample identification number, the reason for testing, whether the food was reported to the Reportable Food Registry, who performed the analysis); and results information (analyte, test method, analytical results, whether the results contradict a label claim or guarantee, and whether action was taken as a result of the sample analysis).

Description of Respondents: Respondents to the collection of information are Federal, State, and Territorial regulatory and public health agency employees with membership access to the Animal Feed Network.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
PETNet	20	5	100	0.25 (15 minutes)	25
LivestockNet	20	5	100	0.25 (15 minutes)	25
SampleNet	20	5	100	0.25 (15 minutes)	25
Total					75

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on our experience with the tracking network over the past 3 years. We estimate that we will receive an average of 5 submissions from 20 respondents for each type of report, and that it will take 15 minutes (0.25 hour) per response.

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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